

CLAIMS

1. An immediate release pharmaceutical tablet with at least two segments, said tablet containing a drug or drugs, in which:

(a) said tablet includes two or more segments and all segments that contain a pharmacologically effective dose of a drug or drug contain the same drug (or combination of drugs at the same ratio);

or,

(b) said tablet includes: (i) a first segment containing a drug or drugs; (ii) a third segment containing a drug (or plurality of drugs) which is (are) different from the drug (or drugs) in said first segment,

and (iii) a second segment that is interposed between said first and third segments and that has an undetectable amount of, or else a pharmacologically ineffective amount of, any drug present in said tablet; (iv) physical and chemical compatibility between said first and third segment;

or,

(c) said tablet includes: (i) a first segment containing a drug (or two or more drugs); (ii) a third segment containing a drugs (or drugs) which are different from the drug or drugs in said first segment; (iii) a second segment that is interposed between said first and said third segment and that has an undetectable amount of, or a pharmacologically ineffective amount of, any drug present in said tablet; and, (iv) said third segment has either or both of the following: a height of at least 2.5 mm or an effective height of at least 1.5 mm.

2. An immediate release pharmaceutical tablet as defined

in claim 1 comprising at least two compositionally distinct segments, with a first segment containing a drug in a pharmacologically effective amount and a second segment that:

- 5 (a) contains the same drug at a lower concentration than the concentration of said drug in said first segment; or
- (b) has no detectable drug or the same drug which is in said first segment in a pharmacologically ineffective amount and also includes a third segment having the same
- 10 drug that is present in said first segment; or
- (c) contains the drug in said first segment and also contains another drug or drugs not present in said first segment; or,
- (d) either has no detectable drug, or lacks any drug or
- 15 drugs in a pharmacologically effective amount, wherein said tablet also comprises a third segment containing a pharmacologically effective quantity of a different drug from the drug that is present in said first segment and wherein said first and third segments are physically and
- 20 chemically compatible;
- or,
- (e) either contains no detectable drug or else contains in a pharmacologically ineffective amount the same drug which is in said first segment; and also includes a third segment
- 25 having a pharmacologically effective dose of a different drug or drugs from said drug (or drugs) that is (are) present in said first segment, said second segment having one or both of the following: a height of at least 2.5 mm or an effective height of 1.5 mm.
- 30 (f) has a pharmacologically effective quantity of a different drug (or drugs) than said drug (or drugs) in said first segment, in which said tablet also includes a third vertically disposed segment having the same drug that is

present in said first segment.

3. An immediate release pharmaceutical tablet as defined in claim 2 wherein the second segment has the same drug at
5 a lower concentration than the concentration of said drug in said first segment.

4. An immediate release pharmaceutical tablet as defined in claim 3 wherein said second segment has a height greater than the combined height of said first segment and said
10 third segment.

5. An immediate release pharmaceutical tablet as defined in claim 3 where a score, perforations, printed marks, or gelatin or a combination of thereof , are placed on or
15 within said second segment and are predominantly horizontally oriented to guide tablet breaking through said second segment substantially without breaking through said first segment or said third segment.

20 6. An immediate release pharmaceutical tablet as defined in claim 2 wherein the second segment contains a combination of the drug in said first segment with another drug or drugs not present in said first segment.

25 7. An immediate release pharmaceutical tablet as defined in claim 2 wherein the second segment contains no detectable drug or the same drug which is in said first segment in a pharmacologically ineffective amount, and wherein said tablet has a third segment having the same drug that is
30 present in said first segment.

8. A immediate release pharmaceutical tablet as defined in claim 7 wherein the concentration of the drug in said first

and third segments is substantially the same.

9. An immediate release pharmaceutical tablet as defined
in claim 8 in which the quantity of drug in said first and
5 third segments is substantially the same.

10. An immediate release pharmaceutical tablet as defined
in claim 8 wherein said first and second segments come
together at an interface which is provided with a
10 separation mark.

11. An immediate release pharmaceutical tablet as defined
in claim 2 having in said second segment no detectable drug
or the same drug which is in said first segment in a
15 pharmacologically ineffective amount, said tablet also
containing a third segment having a different drug from the
drug that is present in said first segment, said third
segment being physically and chemically compatible with
said first segment.

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12. An immediate release pharmaceutical tablet as defined
in claim 3 that contains a separation mark selected from
the group consisting of a score, indicia, printed indicia,
25 a perforation or a band in a second segment or at an
interface between segments.

13. An immediate release pharmaceutical tablet as defined
in claim 2 wherein said second segment has a different drug
30 than the drug in said first segment and also includes a
third segment having the same drug that is present in said
first segment.

14. An immediate release pharmaceutical tablet as defined in claim 13 wherein said second segment has a substantially horizontal separation mark placed on said second segment, along a side of said tablet parallel to the vertical axis of said tablet, said vertical axis being the same as the vertical axis of the tablet die in which the tablet is made.

15. An immediate release pharmaceutical tablet as defined in claim 7 that is derived from three vertically disposed granulations that form three vertically disposed segments, a first segment at the top, a second segment in the middle and a third segment at the bottom and having a substantially horizontal separation mark placed substantially horizontally on or within said second segment.

16. An immediate release pharmaceutical tablet as defined in claim 7 in which said first segment and said third segment are substantially compositionally identical.

17. An immediate release pharmaceutical tablet as defined in claim 7 in which said first segment and said third segment contain substantially identical quantities of the same drug or drugs, where the amount or ratio of said drug or drugs is the same in both segments.

18. An immediate release pharmaceutical tablet as defined in claim 7 in which said second segment is of a color which permits visual identification of said second segment apart from said first segment.

19. An immediate release pharmaceutical tablet as defined in claim 7 in which said second segment contains a separation mark.

5 20. An immediate release pharmaceutical tablet as defined in claim 19 in which said second segment contains indicia.

21. An immediate release pharmaceutical tablet as defined in claim 20 in which said second segment contains printed
10 indicia.

22. An immediate release pharmaceutical tablet as defined in any one of claims 19, 20 or 21 in which breaking said tablet, when guided by color, scoring, or printed indicia
15 yields a tablette having a predetermined quantity of drug.

23. An immediate release pharmaceutical tablet as defined in claim 7 in which the first segment and third segment consist essentially of the same drug.
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24. An immediate release pharmaceutical tablet as defined in claim 11 is provided with a separation mark.

25. An immediate release pharmaceutical tablet as defined
25 in claims 7 or 11 wherein the second segment has a color which permits visual identification of said second segment apart from said first segment and said third segment.

30 26. An immediate release pharmaceutical tablet as defined in claims 7 or 11 in which the second segment corresponds to a segment located in the middle of the tablet.

27. An immediate release pharmaceutical tablet in which the tablet is produced sequentially from a first granulation, a second granulation that contains no detectable drug or a pharmacologically inactive amount of a drug and a third active granulation that is provided with a different active drug or drugs than said first granulation, wherein:

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(a) all granulations in the tablet are physically and chemically compatible;
and/or

(b) the segment derived from the second granulation has an effective height of greater than 4mm.

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28. An immediate release pharmaceutical tablet as defined in claim 27 in which said segment derived from the second granulation has an effective height of from 3-4 mm.

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29. An immediate release pharmaceutical tablet as defined in claim 27 in which said segment derived from the second granulation has an effective height of from 1.5-3 mm.

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30. An immediate release pharmaceutical tablet as defined in claim 27 in which the tablet consists of three segments.

31. An immediate release pharmaceutical tablet as defined in claim 27 in which said second granulation has an amount of drug or drugs which is pharmacologically inactive.

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32. An immediate release pharmaceutical tablet as defined in claim 27 in which other granulations having no detectable active drug or a pharmacologically inactive amount of an active drug are interposed between said first
5 and third granulations.

33. An immediate release pharmaceutical tablet as defined in claim 27 in which said first, second and third granulations have colors which allow for the
10 identification of each tablet segment.

34. An immediate release pharmaceutical tablet as defined in claim 27 in which a segment formed from said second granulation is provided with a separation mark that
15 without limitation may be a substantially horizontally oriented score, indicia, or perforations.

35. An immediate release pharmaceutical tablet as defined in claim 34 in which a segment formed from said second
20 granulation is provided with a score.

36. An immediate release pharmaceutical tablet as defined in claim 34 in which said segment formed from said second granulation is provided with indicia.
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38. An immediate release pharmaceutical tablet as defined in claim 34 in which breaking through said segment formed from said second granulation provides accurate separation of said first segment from said third segment.
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39. An immediate release pharmaceutical tablet as defined in claim 1 wherein said core tablet forms a tablet

structure selected from the group consisting of
A-I-B-I-A, A-I-B-I-B, A-I-B-I-C, or A-B-I-C wherein A, B, C
and I represent mutually different segments that are
vertically disposed upon each other and wherein A, B and C
5 contain an active drug or drugs and I is a segment without
a pharmacologically effective quantity of any drug.

40. An immediate release pharmaceutical tablet as defined
10 in claim 39 in which each of segments A, B, C and/or I
have either a color or indicia which identifies each of
segments A, B, I, and C as being different segments.

41. A method of breaking an immediate release
15 pharmaceutical tablet as defined in claims 12, 13 or 19
which comprises breaking said tablet at said separation
mark.

42. A method of administering a partial dose of a drug
20 contained in a pharmaceutical tablet as defined in claims
12, 13 or 19 comprising breaking said pharmaceutical tablet
at said separation mark to form two or more tablettes and
administering at least one of said tablettes to a patient.

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43. A method of administering a partial dose of a drug
contained in a pharmaceutical tablet, said method
comprising

breaking a pharmaceutical tablet which comprises at
30 least two segments wherein:

(a) a first undivided segment having at least one score,
said segment having a score containing a pharmacologically
effective amount of a drug or drugs and ;

(b) a second segment that adjoins said first undivided segment wherein said second segment contains from an undetectable amount to a maximum of 10% of the concentration of the same drug or drugs in said first
5 segment, said method comprising breaking said tablet at said score to form two or more tablettes and administering at least one of said tablettes to a patient.

44. A pharmaceutical tablet as defined in claim 1 in which
10 said drug or drugs is or are pharmacologically effective in the treatment of cardiovascular conditions, psychiatric conditions, diabetes, thyroid disorders, pain or thrombotic disorders.

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